

WHAT IS CLAIMED IS:

1 1. A method of selectively engaging or penetrating a layer of a luminal organ wall, the luminal
2 organ wall having a plurality of layers including an outermost layer and an innermost layer
3 adjacent to the lumen of the organ, comprising the steps of:

4 a) selecting one of the plurality of layers of the organ wall other than the innermost layer;
5 and

6 b) deploying from within the lumen of the organ a tissue device through the innermost layer
7 to a specific depth to engage or penetrate the selected one of the plurality of layers.

1 2. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim 1,
2 further comprising the step of smoothing the innermost layer of the luminal organ wall prior
3 to step b).

1 3. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim 1,
2 further comprising the step of manipulating the innermost layer of the luminal organ wall to
3 create a substantially flat, single-thickness layer near the desired site of deployment of the
4 tissue device prior to step b).

1 4. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim 2,
2 or 3, wherein another organ is adjacent to the desired site of deployment of the tissue device
3 and further comprising means for creating a gap between the another organ and the desired
4 site of the tissue device prior to step b).

1 5. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim 4,
2 wherein the step of creating a gap includes the steps of:

- 3 i) deploying a tissue device through the innermost layer to one of the other of the
4 plurality of layers of the organ wall; and
5 ii) moving the deployed tissue device away from the another organ to create a gap
6 between the another organ and the desired site of the tissue device.

1 6. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim 2
2 or 3, wherein step a) includes selecting the outermost layer.

1 7. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim 1,
2 wherein step b) includes bringing a deployment mechanism in close contact with the
3 innermost layer from within the lumen of the organ and deploying from the deployment
4 mechanism a tissue device through the innermost layer to a specific depth to engage or
5 penetrate the selected one of the plurality of layers.

1 8. The method of selectively engaging a layer of claim 1, 2, 3, 5, or 7, wherein the organ is a
2 stomach having a wall with at least three layers including an innermost layer or mucosa,
3 muscularis, and outermost layer or serosa and step a) includes selecting one of the muscularis
4 and the outermost layer of the stomach wall.

1 9. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim 8,
2 wherein the innermost layer smoothing or manipulation step includes one of moving the
3 mucosa relative to the underlying muscularis, pressing the mucosa against the muscularis,
4 and distending the stomach wall via insufflation to smooth the innermost layer or mucosa.

1 10. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim 1,
2 2, 3, 5, or 7, further comprising the step of measuring a electrical impedance at multiple
3 locations within the wall and choosing the specific depth based on the impedance data and
4 step b) includes deploying from within the lumen of the organ a tissue device through the
5 innermost layer to the chosen specific depth to engage or penetrate the selected one of the
6 plurality of layers.

1 11. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim 1,
2 2, 3, 5, or 7, wherein the step b) includes the steps of:
3 i) periodically measuring a electrical impedance at a tissue engaging element; and
4 ii) deploying a tissue device through the innermost layer toward the outermost layer of
5 the organ wall until the measured electrical impedance is about equal to a desired
6 value.

1 12. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim 1,
2 2, 3, 5, 7, or 9, wherein said tissue device includes one of a securement and anchoring device.

1 13. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim 4,
2 wherein the depth of the gap is in the range of about 1 to 20 mm and the angle of the sides of
3 the gap relative to the normal to the outer surface at a prior point of engagement to the
4 another organ is in the range of about 0 to 75 degrees.

1 14. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim 4,
2 wherein the depth of the gap and the angle of the sides of the gap are such that they make it
3 less likely that the another organ will conform to, and thereby fill in, the gap.

1 15. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim 1,
2 2, 3, 5, 7, or 9, wherein the tissue device one of incorporates and makes a path for the
3 advancement of one of a securement device, an anchoring device, an implantable device, an
4 electrode, and a conduit for the passage of a fluid, materials or device.

1 16. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim 1,
2 2, 3, 5, 7, or 9, further comprising the step of repeating step b) sequentially or simultaneously
3 to releasably engage at least a first region and second region of the wall and approximating
4 the first and second regions.

1 17. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim 1,
2 2, 3, 5, 7, or 9, further comprising the steps of approximating said two regions of the organ
3 wall and performing step b) to deploy one or more securement elements to secure the two
4 regions together.

1 18. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim
2 17, wherein the regions comprise a segment of the anterior organ wall and a segment of the
3 posterior organ wall and the approximation and securement creates one of a pouch, partition
4 and restriction.

1 19. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim
2 17, wherein said securement elements are comprised of a single suture deployed sequentially
3 through the region.

1 20. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim
2 17, further comprising the step of positioning a biocompatible material between the apposing
3 surfaces of the approximated regions and performing step b) to deploy one or more
4 securement elements to secure the two regions and biocompatible material together.

1 21. The method of selectively engaging or penetrating a layer of a luminal organ wall of claim 1,
2 2, 3, 5, 7, or 9, further comprising the step of performing step b) to attach a first section of a
3 biocompatible material along a first region of the wall and a second section of the material
4 along a second region of the wall to form a partition across the organ's lumen.

22. An apparatus for selectively engaging or penetrating a layer of a luminal organ wall, the luminal organ wall having a plurality of layers including an outermost layer and an innermost layer adjacent to the lumen of the organ, the apparatus comprising means for deploying from within the lumen of the organ a tissue device through the innermost layer to a specific depth to engage or penetrate the selected one of the plurality of layers.

23. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim 22, further comprising means for smoothing the innermost layer of the luminal organ wall.

24. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim 22, further comprising means for manipulating the innermost layer of the luminal organ wall to create a substantially flat, single-thickness layer near the desired site of deployment of the tissue device.

25. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim 23 or 24, wherein another organ is adjacent to the desired site of deployment of the tissue device and further comprising means for creating a gap between the another organ and the desired site of deployment of the tissue device.

26. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim 25, wherein the mean for creating a gap includes:

- i) means for deploying a tissue device through the innermost layer to one of the other of the plurality of layers of the organ wall; and
- ii) means for moving the deployed tissue device away from the another organ to create a gap between the another organ and the desired site of deployment of the tissue device.

27. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim 23 or 24, wherein the outermost layer is the selected layer.

28. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim 22, 23, 24, or 26, wherein the deployment means includes means for bringing the deployment means in close contact with the innermost layer from within the lumen of the organ and means for deploying from the deployment means the tissue device through the innermost layer to a specific depth to engage or penetrate the selected one of the plurality of layers.

29. The apparatus for selectively engaging a layer of claim 22, 23, 24, or 26, wherein the organ is a stomach having a wall with at least three layers including an innermost layer or mucosa, muscularis, and outermost layer or serosa and one of the muscularis and the outermost layer of the stomach wall is selectively engaged.

30. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim 29, wherein the innermost layer smoothing or manipulation means includes means for one of moving the mucosa relative to the underlying muscularis, pressing the mucosa against the muscularis, and distending the stomach wall via insufflation to smooth the innermost layer or mucosa.

31. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim 22, 23, 24, or 26, further comprising means for measuring a electrical impedance at multiple locations within the wall and choosing the specific depth based on the impedance data and the means for deploying includes means for deploying from within the lumen of the organ a tissue device through the innermost layer to the chosen specific depth to engage or penetrate the selected one of the plurality of layers.

32. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim 22, 23, 24, or 26, wherein the means for deploying includes:

- i) means for periodically measuring a electrical impedance at a tissue engaging element;
and
- ii) means for deploying a tissue device through the innermost layer toward the outermost layer of the organ wall until the measured electrical impedance is about equal to a desired value.

1 33. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim
2 22, 23, 24, 26, or 30, wherein said tissue device includes one of a securement and anchoring
3 device.

1 34. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim
2 25, wherein the depth of the gap is in the range of about 1 to 20 mm and the angle of the
3 sides of the gap relative to the normal to the outer surface at a prior point of engagement to
4 the another organ is in the range of about 0 to 75 degrees.

1 35. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim
2 25, wherein the depth of the gap and the angle of the sides of the gap are such that they
3 makes it less likely that the another organ will conform to, and thereby fill in, the gap.

1 36. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim
2 22, 23, 24, 26, or 30, wherein the tissue device one of incorporates and makes a path for the
3 advancement of one of a securement device, an anchoring device, an implantable device, an
4 electrode, and a conduit for the passage of a fluid, materials or device.

1 37. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim
2 22, 23, 24, 26, or 30, further comprising means for employing the means for deploying
3 sequentially or simultaneously to releasably engage at least a first region and second region
4 of the wall and approximating the first and second regions.

38. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim 22, 23, 24, 26, or 30, further comprising means for approximating said two regions of the organ wall and employing the means for deploying to deploy one or more securement elements to secure the two regions together.

39. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim 38, wherein the regions comprise a segment of the anterior organ wall and a segment of the posterior organ wall and the approximation and securement creates one of a pouch, partition and restriction.

40. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim 38, wherein said securement elements are comprised of a single suture deployed sequentially through the region.

41. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim 38, further comprising means for positioning a biocompatible material between the apposing surfaces of the approximated regions and employing the means for deploying to deploy one or more securement elements to secure the two regions and biocompatible material together.

42. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim 22, 23, 24, 26, or 30, further comprising means for employing the means for deploying to attach a first section of a biocompatible material along a first region of the wall and a second section of the material along a second region of the wall to form a partition across the organ's lumen.

43. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim 22, 23, 24, 26, or 30, wherein the one of the tissue penetration element and the tissue engaging mechanism includes one of a hook, barb, harpoon, straight, curved needle, and blade, helical wireform and needle, and a forked element.

44. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim 38, wherein the means for approximating includes a pair of moveable pieces in hinged relationship, each moveable piece being associated with one of the tissue penetration element and the tissue engaging mechanism, said moveable pieces being substantially apart during engagement of the wall by the one of the tissue penetration element and the tissue engaging mechanism, and then moved together to approximate the regions of the wall.

45. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim 44, wherein the means for approximating further includes one of a pull-wire and pneumatic actuator that when activated move the moveable pieces together.

1 46. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim
2 45, further comprising means for modifying the organ wall regions to minimize the amount
3 of dilation that can occur.

1 47. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim
2 46, wherein the means for modifying the organ wall regions includes means for damaging or
3 removing one of the innermost layer and another one of the plurality of layers of the wall.

1 48. The apparatus for selectively engaging or penetrating a layer of a luminal organ wall of claim
2 46, wherein the means for damaging or removing includes one of chemical ablation, thermal
3 ablation, radio frequency treatment, microwave treatment, injection of a sclerosing agent,
4 cryotherapy, and mechanical debridement.